

## Subpart E [Reserved]

## Subpart F—Physical Medicine Therapeutic Devices

890.5050	Daily activity assist device.
890.5100	Immersion hydrobath.
890.5110	Paraffin bath.
890.5125	Nonpowered sitz bath.
890.5150	Powered patient transport.
890.5160	Air-fluidized bed.
890.5170	Powered flotation therapy bed.
890.5180	Manual patient rotation bed.
890.5225	Powered patient rotation bed.
890.5250	Moist steam cabinet.
890.5275	Microwave diathermy.
890.5290	Shortwave diathermy.
890.5300	Ultrasonic diathermy.
890.5350	Exercise component.
890.5360	Measuring exercise equipment.
890.5370	Nonmeasuring exercise equipment.
890.5380	Powered exercise equipment.
890.5410	Powered finger exerciser.
890.5500	Infrared lamp.
890.5525	Iontophoresis device.
890.5575	Powered external limb overload warning device.
890.5650	Powered inflatable tube massager.
890.5660	Therapeutic massager.
890.5700	Cold pack.
890.5710	Hot or cold disposable pack.
890.5720	Water circulating hot or cold pack.
890.5730	Moist heat pack.
890.5740	Powered heating pad.
890.5765	Pressure-applying device.
890.5850	Powered muscle stimulator.
890.5860	Ultrasound and muscle stimulator.
890.5880	Multi-function physical therapy table.
890.5900	Powered traction equipment.
890.5925	Traction accessory.
890.5940	Chilling unit.
890.5950	Powered heating unit.
890.5975	Therapeutic vibrator.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 48 FR 53047, Nov. 23, 1983, unless otherwise noted.

## Subpart A—General Provisions

## § 890.1 Scope.

(a) This part sets forth the classification of physical medicine devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately

described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a physical medicine device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are the chapter I of title 21, unless otherwise noted.

[52 FR 17741, May 11, 1987]

## § 890.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application of premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA